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Attorney Docket No.:2870/319(99.28)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BOARD OF APPEALS AND PATENT INTERFERENCES

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10/1/02

In re Application of: Painter et al.

Serial No.: 09/622,510

Group Art Unit: 1616

Filed: October 19, 2000

Examiner: K. George

For: GEL-BASED COSMETIC COMPOSITION

**BRIEF ON APPEAL UNDER 37 CFR 1.192**

Assistant Commissioner of Patents

Washington, D.C. 20231

Sir:

The following constitutes Applicants' basis for appealing from the rejection of claims 1-26 in the subject application.

1. Real Party in Interest. The real party in interest in this case is Color Access Inc., the assignee of the application.
2. Related Appeals and Interferences. There are no related appeals or interferences.
3. Status of Claims. All claims remain rejected under 35 USC §103(a).
4. Status of Amendments. The amendment dated February 6, 2002, submitted after final rejection, has been entered.
5. Summary of the Invention. The invention relates to cosmetic or pharmaceutical compositions comprising low viscosity, gellant-containing, unstable formulations, which are incorporated into rigid porous supports. The invention also relates to a method of making a cosmetic or pharmaceutical composition comprising preparing a low-viscosity, gellant-containing, unstable formulation, and adding the formulation to a rigid, porous support, as well as compositions made according to this method. As defined in the specification on page 2, lines 33 through page 3, lines 2, the term "unstable" in the present

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context means the formulation is of such low viscosity that it is incapable, on its own, of maintaining an inorganic pigment in suspension. The compositions provide a water-thin, lightweight base which can support the presence of heavy pigments without the necessity for use of thickeners or fillers to support them in the formulation.

6. Issues. The sole issue is whether claims 1-26 are unpatentable as being obvious in view of the combined teachings of Igo-Kemenes et al. US Patent No. 6,001,373 and Iosilevich, US Patent No. 5,137,040.

7. Grouping of claims. Claims 1-26 do not stand or fall together, and are believed to be separately patentable.

8. Arguments.

A. Prosecution History.

The sole rejection in the present application is a rejection of claims 1-26, all the pending claims, as being unpatentable under 35 USC §103(a) in view of the combination of Igo-Kemenes and Iosilevich (each cited above). The initial rejection of the claims, in the office action dated January 3, 2001, was stated as follows:

Igo-Kemenes et al....teaches a cosmetic composition in the form of water-in-oil or oil-in-water emulsion...The composition further contains another desirable component that is a pigment where the pigment can be inorganic or organic...The reference does not teach the gellant as cholesterol derivative..., the composition is impregnated in a support, or the condition that the gel is made.

Iosilevich et al... teaches a make-up applicator formed of a cosmetic sponge material...in which a cosmetic substance such as a pigmented gel, liquid powder or other substance is impregnated within.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the invention of Igo-Kemenes et al. which teaches a gel or emulsion containing pigments in the invention of Iosilevich et al. which teaches a make-up pad which can be impregnated with a pigmented gel composition. It would also have been obvious [to] select a gellant that would provide the best conditions for a low viscosity gel and to provide conditions in the process of preparing the gel whereby it does not gel until it is within the support.

In response to this rejection, Applicants have made the argument that neither of the references cited, either alone or in combination provided any teaching or suggestion of the desirability of making and using a low viscosity, unstable formulation, let alone a teaching as to how to make one that would function properly in a porous support as required by the present claims. In response to Applicants' arguments, in the final rejection dated August 24, 2001, the Examiner stated:

It is the position of the examiner that the composition of the prior art [i.e., the Igo-Kemenes reference] can be unstable as it teaches the same composition as claimed. The composition is in the form of a water-in-oil formulation, contains an oil phase, gellant, a pigment, and substantially no waxes or suspending agents..

In their response to this final rejection, Applicants noted that the Examiner's assertion of the instability of the Igo-Kemenes reference is insupportable, given that the document is replete with references to the stability of the claimed composition, and that the Iosilevich reference also contained no reference to an unstable formulation.

In response, and upon consideration of Applicants' reply, in the Advisory Action dated March 28, 2002, the Examiner simply states, without addressing Applicants' arguments:

[I]t is the position of the Examiner that the prior art combination of Igo-Kemenes et al. in view of Iosilevich et al. does disclose the claimed invention.

Applicants subsequently filed a Notice of Appeal, and now present their arguments on appeal.

**B. Arguments in response to rejection under 35 USC § 103**

To briefly recap the nature of the invention, as defined in its broadest embodiments, the invention is directed to (i) cosmetic and pharmaceutical compositions, the composition comprising a non-rigid, porous support (such as sponge) in which a low-viscosity, gellant-containing, otherwise unstable cosmetic or pharmaceutical formulation is incorporated, (ii) a method of making cosmetic and pharmaceutical compositions comprising preparing a low viscosity, gellant-containing, otherwise unstable formulation; and incorporating the formulation into a porous, elastic, non-rigid support, and (iii) compositions made by this method. The compositions and methods are unique in that the formulation component of the composition is in itself very low viscosity and standing on its own, unstable, i.e., it is deliberately formulated in such a way as to be incapable of stably supporting any substantial weight due to solids, such as inorganic pigments, in the formula. This instability is achieved, by the use of very low levels of gellant, i.e., below the levels needed to substantively increase the viscosity of the product (see page 3, lines 3-18 of the specification), and/or by reduction or elimination of thickeners and waxes normally used in such formulations to enhance stability (page 5, lines 26-31). The instability of the formulation renders it, on its own, an essentially commercially non-viable product. However, when added to the porous support, the formulation not only becomes viable, but provides a unique advantage over other liquid formulations: the product applied by the

user is lightweight, smooth and silky, without the pasty, waxy texture that can characterize fully gelled, wax- or thickener-containing products. While preparing an inherently unstable formulation is counterintuitive to the person skilled in the art of formulation, Applicants have taken a disadvantage and turned it to an advantage, by combining the unstable formula with a porous support, resulting in an elegant, useful formulation that is stabilized by its incorporation into the porous support. Applicants believe that the composition itself, as well as the method of making it, is unique.

The prior art cited by the Examiner unequivocally does not disclose any such compositions or methods. The primary reference, Igo-Kemenes, does describe a formulation that contains certain elements of the present formulation, i.e., it does contain gellants, and may contain pigments. However, it does not disclose an unstable formulation. The Examiner has taken the position that because Igo-Kemenes teaches a composition containing some of the same components as Applicants' formulation, namely, according to the Examiner, "an oil phase, a gellant, a pigment, and substantially no waxes or suspending agents", the Igo-Kemenes composition "can be unstable". The Examiner is essentially stating that because certain components of the formulation of the present claims are found in the formulations of Igo-Kemenes, the prior art formulations must be, or at the very least may be, implicitly unstable. However, this isolation of the teaching of four generic components, without the reviewing the context in which they appear in the document as a whole, is clearly an erroneous analysis that cannot withstand careful legal scrutiny. *In re Fine*, 5 USPQ 2d 1596 (Fed.Cir. 1988). It is well-established that the prior art teachings must be considered in the context of the teachings of the entire reference; it is further required that a rejection cannot be predicated on the mere identification in the prior art reference of individual components of the claimed invention. *In re Kotzab*, 54 USPQ 2d 1313, 1317 (Fed. Cir. 2000). In the present case, the Examiner is culpable of both these prohibited activities.

First, a careful reading of the entirety of Igo-Kemenes will clearly show that the reference only teaches the desirability and manufacture of a stable composition. Attention is drawn first to column 5, line 65 through column 6, line 16, wherein the gellant of the composition is discussed. The authors specifically recommend one particular type of gellant, and recommend specified amounts. In lines 12-14, the authors particularly note that this specific gellant is quite valuable to the composition from the viewpoint of "improving emulsion stability"(emphasis added). Can one skilled in the art read this passage and rationally believe that the authors have herein taught use of the gellant in such a way to produce an unstable composition? Lest this evidence not be considered adequate to show the unequivocal teachings of this patent, however, attention is further directed to column 8, line 53 through column 9, line 23, wherein the authors note that it is desirable to include yet another gelling

agent for the express purpose of “providing excellent stability characteristics”. Again, can there be any doubt that this reference is teaching anything but the making of a stable composition?

The Examiner perceives that the use of similar elements in Igo-Kemenes and the present application must necessarily result in the same composition. This conclusion could only be reached, however, if one is picking and choosing the isolated words from the text, and fails to read the words that surround them. Igo-Kemenes is clearly intending to use the noted elements to make a stable composition, and gives a disclosure of the way in which those elements can be combined so as to lead to the production of a stable composition. As just one example, the prior art document teaches the preference for incorporating high viscosity components (see, for example, column 1, lines 35-39; column 5, line 9-10; and column 8, lines 57-60); this is in direct contrast to the present disclosure, which explicitly recommends a low viscosity formulation. In the absence of any other evidence to the contrary, the Igo-Kemenes reference must be taken at face value and be presumed to teach what it says it teaches, namely, a stable composition. On the other hand, the present disclosure teaches how to take the same elements and make an unstable composition. These two opposite results are not inconsistent if one skilled in the art reads each disclosure carefully in its entirety, and follows their respective teachings. It is of course possible to take the cited components of Igo-Kemenes and make an unstable formulation, but only if one ignores the entire remainder of the document; similarly it is also possible for one to make a stable formulation from Applicants’ elements if one chooses to completely disregard the rest of the teachings of the application and focus only on the components. However, this would not be a technically rational or legally proper analysis for a determination of obviousness. Unfortunately, this is exactly the type of analysis the Examiner has made in this case, and it is indisputably unacceptable. As the foregoing arguments plainly show, and contrary to the Examiner’s assertion, the primary reference fails to disclose a crucial element of the present claims, i.e., a gellant-containing formulation that is unstable in the absence of a support.

Turning to Iosilevich, one will also fail to find any teaching of an unstable formulation. Iosilevich does indeed teach incorporating cosmetic compositions into a porous support. The disclosure of the compositions is quite limited, in that it refers to “pigmented gels, dry or liquid powders, and other light creams” (column 1, lines 36-37). The reference is, however, entirely silent on the components or how to make such compositions, and is also silent, at least explicitly, as to the stability (or lack thereof) of the recited compositions. It unquestionably does not disclose the desirability of making unstable compositions, nor the desirability of incorporating unstable compositions into the porous supports. If anything can be gleaned from the teachings, it would have to be assumed that the compositions used are intended to be stable, however, for two reasons: (1) a

stable composition is the holy grail of cosmetics, and no one skilled in the art would imply the recommended use of an unstable composition without an explicit suggestion; and (2) it can be presumed that the compositions would be thickened adequately so as to be stable, since the reference teaches, in column 3, lines 43-45, that the "substance"(i.e., the cosmetic) is absorbed into "only a portion" of the applicator, whereas, in contrast, with the very low viscosity formulations of the present invention, "the entire formulation is distributed integrally throughout the support" (Applicants' specification, page 2, lines 27-28). However, it is not even necessary to come to these conclusions to accept Applicants' arguments: the document simply does not teach the use of an unstable formulation in a porous support, and indeed, the Examiner has not suggested that it does.

What, then, is the result of the combination of the teachings of the two references? Even if one directly combines the teachings of the two documents, at best one skilled in the art would find the suggestion for incorporation of a stable formulation into a porous support, since the Igo-Kemenes reference teaches only stable composition. Between the two references there is absolutely no suggestion whatsoever of an unstable formulation, that an unstable formulation might be in any way desirable, or how to make an unstable formulation suitable for combination with a porous support. Establishment of a *prima facie* case of obviousness requires, *inter alia*, that prior art reference(s) teach or suggest all claim limitations. *In re Royka*, 180 USPQ 580 (CCPA 1974). In the utter absence of this crucial teaching in the cited prior art, no *prima facie* case of obviousness has been made, and therefore, all the present claims, each of which require the presence of an unstable formulation must be considered unobvious. Applicants' arguments to this effect have already been provided to the Examiner, and have remained un rebutted by the Examiner, who instead of addressing the arguments, has chosen to make the conclusory statement that "it is the Examiner's position that the prior art ...does disclose the claimed invention". Such conclusory statements, without support, cannot sustain an obviousness rejection. *In re Lee*, Fed Cir. 61 USPQ 2d 1430 (Fed. Cir. 2002). In view of the foregoing discussion and arguments presented, it is clear that the present rejection has no legal or technical basis, and therefore must be reversed by the Board.

Although the foregoing arguments are sufficient to establish the patentability of the independent claims, and therefore of all the claims dependent thereon, Applicants believe that certain of the dependent claims are separately patentable. In particular, Applicants believe that claims 4, 6, 7, 8, 15, 16, 21, 23, 24, 25 and 26 contain subject matter which is separately patentable from the independent claims 1 and 14. Indeed, in the rejections, the Examiner has focused primarily on the components of the independent claims, and in several cases, has made no reference at all to the obviousness of the specific subject matter of these claims. With regard to claim 4, this claim requires

that the formulation be anhydrous, i.e., it is a single phase formulation containing no water. The basis for the Examiner's rejection notes that Igo-Kemenes teaches water-in-oil or oil-in-water emulsions, but the Examiner has not shown any evidence of the obviousness of an anhydrous formulation, or that emulsions and single phase compositions are functionally equivalent. Indeed, as the specification notes on page 1, lines 17-22, it is particularly difficult to make a useful single phase composition capable of holding pigment without the presence of waxes or other stabilizers; thus, Applicants' preparation of such a product is particularly unexpected. In the absence of any showing by the Examiner of the obviousness of this subject matter, this claim must be considered unobvious.

Claims 6, 7, 8, 21, 23, 24 and 26 each are directed to specifying the identity of the gellant used. Claims 6 and 21 each provide a list of oil-phase gellants that includes cholesterol and derivatives thereof, dextrin fatty acid esters, silicone gellants, oil-soluble cellulose derivatives, and oil-soluble polymers. Claims 7 and 23 specify the gellant is a cholesterol derivative, and claims 8, 24 and 26 specify that the gellant is lanosterol. In the rejection dated January 3, 2001, the Examiner even expressly stated that the Igo-Kemenes reference does not disclose a cholesterol derivative (let alone any of the others that are claimed in claims 6 and 21), yet has asserted in the same rejection that "it would have been obvious [to] select a gellant that would provide the best conditions for a low viscosity gel...". As Applicants pointed out in response to that office action, there was absolutely no support provided by the Examiner for why the selection of a particular gellant would have been obvious, particularly in view of the cited reference teaching stable formulations rather than unstable ones, as Applicants require. The Igo-Kemenes reference discloses one, and only one, type of oil gellant, and that is aluminum-magnesium-hydroxy stearate. This gellant does not fall into any of the categories claimed in claim 6, let alone the more specific categories of claims 7, 8, 23, 24 and 26. Nor has the Examiner provided any evidence whatsoever that Applicants' claimed gellants are functional equivalents of the Igo-Kemenes gellant, or even that a functional equivalent of the Igo-Kemenes gellant, which is used to create a stable formulation, would be useful in creating an unstable formulation. Once again, the Examiner has relied solely on a conclusory statement, with no backup evidence to support it, in this obviousness rejection; clearly this is legally inadequate to establish the obviousness of this group of claims (see *In re Lee, supra*), and therefore the rejection of claims 6, 7, 8, 21, 23, 24 and 26 must be reversed.

Claims 15 and 16 relate to specific conditions of making the compositions of the invention. Claim 15 requires that the formulation is prepared under conditions that do not permit gelling of the formula, and claim 16 requires that the formulation is gelled only within a support. That this is neither taught or suggested by Igo-Kemenes or Iosilevich is unquestionable, and indeed the Examiner

acknowledges that the "condition that the gel is made" is not disclosed (office action dated January 3, 2001, quoted above). The utter lack of such a disclosure anywhere in the cited prior art has not stopped the Examiner from concluding, once again without any factual or technical support, that it would have been obvious "to provide conditions in the process for preparing the gel whereby it does not gel until it is within the support". How this is obvious from either of the pieces of prior art cited is unclear to Applicants, and no explanation has been forthcoming from the Examiner, notwithstanding Applicants' request for clarification in Applicants' response to the rejection. In fact, the subject matter of these two claims is utterly unobvious in view of these documents. First, the Iosilevich reference does not provide any teaching whatsoever as to gelling of formulations, so therefore provides no support for the rejection. Igo-Kemenes, which does disclose gelling of formulations, particularly notes, as shown above, the importance to the stability of the product of having the formulation properly gelled. Thus, no reasonable individual could read this document and find a suggestion to prevent or delay gelling in the formulation, or any motivation why doing so should be desirable. In the absence of such teaching or suggestion to be found in the prior art, the rejection of claims 15 and 16 must be reversed.

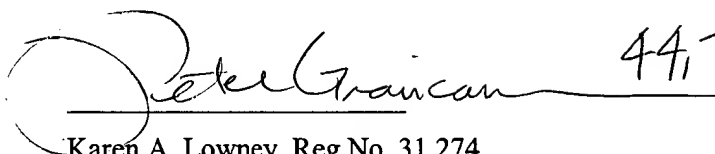
Finally, claim 25 claims a composition comprising an elastic, non-rigid porous support into which a low-viscosity, cholesterol or cholesterol derivative gellant-containing, otherwise unstable formulation has been integrated, the formulation also comprising at least one inorganic pigment, and an anhydrous base. This claim incorporates a combination of elements that have been addressed individually in other claims that have been discussed above. The individual elements alone, for example, the cholesterol-based gellant, and the anhydrous base, in the context of the independent claims, have been shown above to be unobvious in the context of the independent claims 1 and 14. Since the individual elements alone have been shown not to be taught or suggested by the prior art, then clearly their combination, as claimed in claim 25, must also be considered unobvious. In any case, the Examiner has made no showing at all as to how the combination of elements in claim 25 is obvious in view of Igo-Kemenes and/or Iosilevich, and without such showing, the obviousness of this claim cannot be maintained.

### CONCLUSION

Applicants have shown, by the foregoing arguments and citations, that the PTO has not borne its burden of establishing obviousness of claims 1-26 of the present application. Applicants therefore respectfully request that the Board reverse the holding of obviousness under 35 USC §103(a), and pass the present claims to issue.



Respectfully submitted,

 44,706

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Appendix: The appealed claims

1. A cosmetic or pharmaceutical composition comprising a non-rigid, porous support in which a low-viscosity, gellant-containing, otherwise unstable cosmetic or pharmaceutical formulation is incorporated.
2. The composition of claim 1 which comprises an oil phase.
3. The composition of claim 1 in which the formulation is a water-and-oil emulsion.
4. The composition of claim 2 which is anhydrous.
5. The composition of claim 2 in which the base comprises a silicone oil.
6. The composition of claim 2 in which the gellant is selected from the group consisting of cholesterol and derivatives thereof, dextrin fatty acid esters, silicone gellants, oil-soluble cellulose derivatives, and oil-soluble polymers.
7. The composition of claim 6 in which the gellant is a cholesterol derivative.
8. The composition of claim 7 in which the gellant is lanosterol.
9. The composition of claim 1 in which the porous support has a pore size of from about 100 to about 300 pores per inch.
10. The composition of claim 1 in which the porous support is made of a material selected from the group consisting of a natural sponge, a foamed rubber or a foamed polyethylene.

11. The composition of claim 1 which also contains at least one pigment.
12. The composition of claim 11 which comprises an inorganic pigment.
13. The composition of claim 1 which contains substantially no waxes or suspending agents.
14. A method for making a cosmetic or pharmaceutical composition comprising (a) preparing a low viscosity, gellant-containing, otherwise unstable formulation; and (b) incorporating the formulation into a porous, elastic, non-rigid support.
15. The method of claim 14 in which the formulation is prepared under conditions which do not permit gelling of the formulation.
16. The method of claim 15 in which the formulation is permitted to gel within the support.
17. A composition prepared according to the method of claim 14.
18. A composition prepared according to the method of claim 15.
19. A composition prepared according to the method of claim 16.
20. The composition of claim 17 in which the formulation comprises an oil.
21. The composition of claim 20 in which the gellant is selected from the group consisting of cholesterol derivatives, dextrin fatty acid esters, silicone gellants, and oil-soluble polymers.

22. The composition of claim 21 in which the oil comprises a silicone oil.
23. The composition of claim 21 in which the gellant is a cholesterol derivative.
24. The composition of claim 21 in which the gellant is lanosterol.
25. A cosmetic composition comprising an elastic, non-rigid porous support into which a low-viscosity, cholesterol or cholesterol derivative gellant-containing, otherwise unstable formulation has been integrated, the formulation also comprising at least one inorganic pigment, and an anhydrous base.
26. The composition of claim 23 in which the gellant is lanosterol.